

Docket No.: 029869.00003-US01
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Francis P. Kuhajda et al.

Application No.: 10/533,311

Group Art Unit: Not Yet Assigned

Filed: April 29, 2005

Examiner: Not Yet Assigned

For: A METHOD FOR INHIBITING CANCER
DEVELOPMENT BY FATTY ACID
SYNTHASE INHIBITORS

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Listed on accompanying Form PTO/SB/08a/b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO/SB/08a/b based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior

art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith. It is further understood that the Examiner will consider information that had been cited by or submitted to the U.S. Patent and Trademark Office in a prior application relied on under 35 U.S.C. § 120. 1138 OG 37, 38 (May 19, 1992).

Applicants have checked the appropriate boxes below.

- ☒ 1. This Information Disclosure Statement is being filed within three months of the U.S. filing date OR before the mailing date of a first Office Action on the merits. No statement under 37 C.F.R. § 1.97(e) or fee is required.
- ☐ 2. This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection or Notice of Allowance.
 - ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
 - ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).

- ☐ c. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 3. This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. It is hereby requested that the Information Disclosure Statement be considered. Attached is our Check No. _____ in the amount of \$ _____ in payment of the fee under 37 C.F.R. § 1.17(i).
- ☐ a. I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 4. Relevance of the non-English language document(s) is discussed in the present specification.
- ☐ 5. The document(s) was/were cited in a corresponding foreign application. An English language version of the foreign search report is attached for the Examiner's information.
- ☐ 6. A concise explanation of the relevance of the non-English language document(s) appears below:
- ☐ 7. The Examiner's attention is directed to co-pending U.S. Patent Application No. _____, filed _____, which is directed to related technical subject matter. The identification of this U.S. Patent Application is not to be construed as a waiver of secrecy as to that application now or upon issuance of the present application as a patent. The

Examiner is respectfully requested to consider the cited application and the art cited therein during examination.

- ☐ 8. Copies of the documents were cited by or submitted to the Office in Application No. _____, filed _____, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a/b, and to indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 50-0740 referencing Docket No. 029869.00003-US01.

Dated: April 7, 2006

Respectfully submitted,

By 

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Attorney for Applicant

Substitute for form 1449A/B/PTO		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/533,311-Conf. #5370
		Filing Date	April 29, 2005
		First Named Inventor	Francis P. Kuhajda
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet 1 of 2	Attorney Docket Number	029869.00003-US01	

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	Foreign Patent Document Country Code ³ -Number-Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	⁴

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS					
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.			²
/S.J./	CA	ANDERSEN, J.A., Lobular Carcinoma in Situ, Acta path. microbiol. scand., Sect. A, 82, 519-533 (1974).			
/S.J./	CB	ARSLANIAN, M. J. ET AL., Fatty Acid Synthase from Chicken Liver, Methods in Enzymology, 35:59-65 (1975).			
/S.J./	CC	ATKIN, W.S. ET AL., Long-Term Risk of Colorectal Cancer After Excision of Rectosigmoid Adenomas, The New England Journal of Medicine, 326(11):658-662 (1992).			
/S.J./	CD	BETSILL, W.L. et al., INTRADUCTAL CARCINOMA, JAMA, 239(18):1863-1867 (1978).			
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/S.J./	CF	CARTER, C.L., A Prospective Study of the Development of Breast Cancer in 16,692 Women with Benign Breast Disease, American Journal of Epidemiology, 128(3):467-477 (1988).			
Not provided	CG	CARTER, C. ET AL., Tumors and Tumor-Like Lesions of the Lung, Major Problems in Pathology, 30 at 120-147 (1990).			
/S.J./	CH	CRISSMAN, J.D. ET AL., Squamous Intraepithelial Neoplasia of the Upper Aerodigestive Tract, 1-17 (Douglas R. Gnepp, M.D. ed., W.B. Saunders Company, 2000).			
/S.J./	CI	DILS, R. et al., Fatty Acid Synthase from Rabbit Mammary Gland, Methods Enzymol., 35:74-83 (1975).			
/S.J./	CJ	DUPONT, W.D. ET AL., Breast Cancer Risk Associated with Proliferative Disease, Age at First Birth, and a Family History of Breast Cancer, American Journal of Epidemiology, 125(5):769-779 (1987).			
/S.J./	CK	FUNABASHI, H. ET AL., Binding Site of Cerulenin in Fatty Acid Synthetase, J. Biochem., 105(5):751-755 (1989).			
/S.J./	CL	GLOCKNER, S. ET AL., Amplification of Growth Regulatory Genes in Intraductal Breast Cancer is Associated with Higher Nuclear Grade but Not with the Progression to Invasiveness, Laboratory Investigation, 81(4):565-571 (2001).			
/S.J./	CM	GOLDMAN, H., Mucosal Hypertrophy and Hyperplasia of the Stomach, Pathology of the Gastrointestinal Tract, 577-586 (Si-Chun Ming and Harvey Goldman eds., Williams & Wilkins, 1998).			

Examiner Signature	Date Considered
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.J./

Substitute for form 1449A/B/PTO		Complete If Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)		Application Number	10/533,311-Conf. #5370
		Filing Date	April 29, 2005
		First Named Inventor	Francis P. Kuhajda
		Art Unit	N/A
		Examiner Name	Not Yet Assigned
Sheet	2	of	2
		Attorney Docket Number	029869.00003-US01

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/S.J./	CO	KAMIYA, T. ET AL., Long-Term Follow-Up Study of Gastric Adenoma and Its Relation to Gastric Protuded Carcinoma, CANCER, 50(11):2496-2503 (1982).	
/S.J./	CP	KRONZ, J.D. ET AL., Predicting Cancer Following a Diagnosis of High-Grade Prostatic Intraepithelial Neoplasia on Needle Biopsy, The American Journal of Surgical Pathology, 25(8):1079-1085 (2001).	
/S.J./	CQ	LAXEN, F., Gastric Carcinoma and Pernicious Anaemia in Long-Term Endoscopic Follow-up of Subjects with Gastric Polyps, Scand. J. Gastroenterol, 19:535-540 (1984).	
/S.J./	CR	LOFTS, F.J. ET AL., Cancer Treatment and Research, 61:161-79 (1992).	
/S.J./	CS	MILGRAUM, L.Z. ET AL., Enzymes of the Fatty Acid Synthesis Pathway Are Highly Expressed in <i>In Situ</i> Breast Carcinoma, Clinical Cancer Research, 3:2115-2120 (1997).	
/S.J./	CT	OWEN, D.A. ET AL., Pathology of the Gallbladder, Biliary Tract and Pancreas, Major Problems in Pathology, 39 at 337 (2001).	
/S.J./	CU	PAGE, D.L. ET AL., Atypical Hyperplastic Lesions of the Female Breast, Cancer, 55:2698-2708 (1985).	
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/S.J./	CW	PAGE, D.L. ET AL., Noninfiltrating (<i>In Situ</i>) Carcinoma, The Breast 169-192 (Kirby I. Bland and Edward M. Copeland, III eds., W.B. Saunders Company (1991)).	
/S.J./	CX	PIZER, E.S. ET AL., Increased Fatty Acid Synthase as a Therapeutic Target in Androgen-Independent Prostate Cancer Progression, The Prostate, 47:102-110 (2001).	
/S.J./	CY	PIZER, E.S. ET AL., Malonyl-Coenzyme-A Is a Potential Mediator of Cytotoxicity Induced by Fatty-Acid Synthase Inhibition in Human Breast Cancer Cells and Xenografts, Cancer Research, 60:213-218 (2000).	
/S.J./	CZ	ROSEN, P.P., Lobular Carcinoma <i>In Situ</i> and Atypical Lobular Hyperplasia, Rosen's Breast Pathology, 581-626 (2d ed. Lippincott Williams & Wilkins 2001.).	
/S.J./	CA1	SCHEPMAN, K.P. ET AL., Malignant Transformation of Oral Leukoplakia: A Follow-up Study of a Hospital-Based Population of 166 Patients with Oral Leukoplakia from The Netherlands, Oral Oncology, 34(270-275 (1998).	
/S.J./	CB1	WAKIL, S.J., Fatty Acid Synthase, A Proficient Multifunctional Enzyme, Biochemistry, 28(11):4523-4530 (1989).	

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Samira Jean-louis/	Date Considered	07/06/2009
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ALL REFERENCES CONSIDERED EXCEPT WHERE LINED THROUGH. /S.J./